UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

BIOLUMIX, INC., ET AL.,

Plaintiffs/Counter-Defendants,

v.

CENTRUS INTERNATIONAL, INC.,

Defendant/Counter-Plaintiff.
_____/

Case No. 08-11418

SENIOR UNITED STATES DISTRICT JUDGE ARTHUR J. TARNOW

MAGISTRATE JUDGE R. STEVEN WHALEN

ORDER DENYING DEFENDANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT [209] AND GRANTING IN PART AND DENYING IN PART PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT [212]

Plaintiffs Biolumix, Inc., Gideon Eden, and Ruth Eden brought suit against Centrus International, Inc. seeking declaratory judgment that Plaintiffs did not infringe on various patents registered by Defendant, did not engage in unfair competition with Defendant, did not violate contracts, did not infringe on trademarks of Defendant, and that Plaintiff are the rightful owners of various patents.

Now before the Court are Plaintiffs' Objections [228] and Defendant's Objections [225] to the Report of the Special Master [217] recommending that the Court grant summary judgment to Plaintiffs on the issue of non-infringement of the "'576 patent" and grant summary judgment to Defendant on the issue of infringement of the "'873" patent.

For the reasons stated below, Defendant's Motion for Summary Judgment [209] is **DENIED**. Plaintiffs' Motion for Summary Judgment [212] is **GRANTED** as to the '576 patent and **DENIED** as to the '873 patent.

I. Procedural and Factual Background

This case was originally filed in April 2008. Plaintiffs Ruth and Gideon Eden are owners of Biolumix, Inc.. Prior to founding Biolumix, both Edens worked at BioSys, Inc., a predecessor of the current Defendant, Centrus, Inc. While at BioSys, the Edens developed a number of patents which were assigned to BioSys and are now owned by Defendant. The Edens left BioSys and, in 2006, Ruth Eden founded Biolumix to develop new products and technologies. Most important to the present litigation, Ruth Eden developed two new products, the "BioLumix," a microbiological testing device, as well as a "Four-Legged Vial" for use with the BioLumix device. These products compete in the marketplace with products of the Defendant and are the Biolumix products Defendant, in its Counterclaim, alleges infringes on its own products.

Plaintiffs, in their Second Amended Complaint, filed April 12, 2010, allege thirteen claims involving patent infringement and validity, breach of contract, trademark infringement and other related matters. Defendant, in a Counterclaim filed April 14, 2010, alleges forty-one claims involving patent infringement and validity, breach of contract, trademark infringement, civil conspiracy and other related matters.

After numerous motions, referral to arbitration, and appeal of certain issues to the Federal Circuit, the present case was, by stipulated Order [63] on February 5, 2010, referred to a Special Master. On May 31, 2012, the Court issued an Order [187] adopting a Report of the Special Master and granting Plaintiffs' Motion for Partial Summary Judgment with respect to the non-infringement of two patents related to "Four-Legged Testing Vials." In addition, the Court denied Plaintiffs' motion with respect two patents, the '576 and '873 patents. These two patents are now the subject of motions for partial summary judgment by Plaintiffs [212] and Defendant [209].

The '873 patent, owned by Defendant, is a device used to detect contaminating micro-organisms in food, water, or pharmaceuticals. The device uses a transparent plastic container or vial to hold the fluid to be tested. At the bottom of the container is a layer of "semi-fluid substance," specifically, agar. Agar is a transparent "gelling agent," the purpose of which is to "provide a barrier to solid substances into the fluid." In addition, when testing for the presence of micro-organisms, light is transmitted from a lamp on the device through both the fluid and agar "barrier layer" to a light detector, which analyzes the data to determine if there is contamination.

Claim 1 of the '873 patent is for a "device for detecting microbial growth from a sample substance," said device being comprised of:

> (1) a container which is at least partially transparent and includes an inner chamber;
> (2) a fluid layer contained within said container for cultivating microorganisms therein, said fluid layer having a volume;
> (3) a soluble growth media and at least one indicator substance mixed with said fluid layer for undergoing transformation in the presence of microorganism growth; and
> (4) (a) a barrier layer having a volume smaller than said volume of said fluid layer contained within said container adjacent to said fluid layer, said barrier layer composed of a matrix phase containing a fluid which contains at least one indicator substance and soluble growth media essentially identical to that contained in said fluid layer, said barrier layer fluid being in equilibrium with said fluid layer, said barrier layer providing a barrier to solid substances introduced into said fluid layer while providing a fluid zone within said matrix which facilitates change in said indicator substance and growth media contained in said fluid in said matrix, said change occurs and can be detected in said indicator substance contained in said fluid in said matrix due to microbial growth occurring in said fluid layer.

Pursuant to an Order [180] accepting the Special Master's Report [147] on *Markman* claim construction, "barrier layer," which refers to the layer of agar in Defendant's device, is defined as "a semi-fluid substance comprised of gel material, having a fluid portion with the same composition as the fluid layer." "Barrier" is defined as "the semi-fluid substance which prevents solids from entering the barrier layer." "Matrix" is defined as "materially synonymous with barrier layer."

The '576 patent is related to the '873 patent, and is an instrument "capable of providing simultaneous optical readings of multiple test vials containing different samples." It assists in the calibration of the light-detection system of the '873 system, and provides "an automatic calibration scheme which compensates for the parametric differences among the test vial locations."

Claim 1 of the '576 patent is for "an instrument for detecting microbial growth in test vials containing growth media and dye material," composed of:

> (1) a multiplicity of light-sensor combinations, each combination comprising at least one light source and at least one light detector positioned at the location of each of the test vials, said light detector positioned relative to said light sensor to detect light emitted from the dye material when said light source illuminates said dye material;
>
> (2) calibration means for compensating differences among the output values of said light detector for each said combination, said calibration means providing similar output levels of said light detectors for said test vials having identical compositions of said media and said dye material;
>
> (3) a driver means for separately driving each said light source at a specific energy level;
>
> (4) a processor means for controlling said driver means;
>
> (5) an algorithm embedded in said processor means, providing compensated output values of said light detectors and applying a mathematical transformation to the output of said light detectors to reduce parametric differences among the output values of said light detectors resulting from the combined performance differences among said light source and light detector combinations;
>
> (6) said algorithm comprising the formula: $Y=X(U-L)/(OL-LL) + U-OL(U-L)/(OL-LL)$, wherein: X is the output from said light source;
> Y is said compensated value; U is a desired maximal level common to all said compensated levels; L is a desired minimal level common to all said compensated levels; OL is the output of said light detector receiving energy directly from the light source when said test vial is being removed; and LL is the output of said light detector when said light source is driven by said driver means at a level representing the minimal energy obtained from said light detector for any of said test vials.

Pursuant to the Order [180] accepting the Special Master's Report [147] on *Markman* claim construction, "calibration means" is defined as "a driver for separately driving each light source at

a specific energy level; a microprocessor that controls the driver; and a calibration algorithm for compensation for the difference in the output signals among the light-sensor pairs," the algorithm being the one algorithm presented above. "OL . . . when said test vial is being removed" is clarified to mean "OL . . . when no test vial is positioned between the source and the sensor." "Test vial(s)" is defined as "vial(s) containing samples to be tested for microbial growth, growth media, and dye material."

On September 5, 2012, the Special Master issued a Report [217] finding that summary judgment should be granted to Plaintiffs with respect to non-infringement of the '576 patent (the "testing instrument"), and that summary judgment should be granted to Defendant with respect to a finding of infringement by Plaintiffs of the '873 patent (the "membrane vial"). Both Plaintiffs and Defendant have filed objections to the Special Master's Report.

II. Standard of Review

Federal Rule of Civil Procedure 53 governs the appointment and functions of Special Masters. This Court reviews *de novo* all objections to findings of fact made or recommended by the Master, and decides *de novo* all objections to conclusions of law made or recommended by the Master. Fed R. Civ. P. 53(f).

A motion for summary judgment is granted under Fed. R. Civ. P. 56(c) when there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. Summary judgment is also proper where the moving party shows that the non-moving party is unable to meet its burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 326 (1987). Facts and inferences must be viewed in the light most favorable to the non-moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986). However, the non-moving party must present "specific facts showing that there is a genuine issue for trial," and must demonstrate that

there is more than "some metaphysical doubt as to the material facts." *Moore v. Philip Morris Cos., Inc.*, 8 F.3d 335, 339-40 (6th Cir. 1993) (internal citations omitted).

III. Plaintiffs' Objections

Plaintiffs object to the Special Master's finding that they infringed on the '873 patent, the "membrane vial." First, Plaintiffs argue that the Special Master misapplied "the doctrine of equivalents" at the summary judgment stage. Second, Plaintiffs criticize the Special Master's comment in his Report that their device was intended to "design around" the '873 patent. Third, Plaintiffs criticize generally the Special Master's weighing of the evidence. Fourth, Plaintiffs argue that the Special Master did not properly apply "prosecution history estoppel" to Defendant's claim regarding the '873 patent.

A. First Objection - Misapplication of the "Doctrine of Equivalents"

The doctrine of equivalents is described in *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). Under this doctrine "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and . . . the patented invention. *Id.* at 21 (citing *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 609 (1950)). What constitutes equivalency "must be determined against the context of the patent, the prior art, and the particular circumstances of case. Equivalence . . . does not require complete identity for every purpose and in ever respect . . . [a]n important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was." *Graver Tank*, 339 U.S. at 609. The doctrine "must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson*, 520 U.S. at 29. A determination of infringement or non-infringement under the doctrine of

equivalents is a question of fact. *Roche Palo Alto LLC v. Apotex, Inc.*, 531 F.3d 1372, 1377 (Fed. Cir. 2008) (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1124 (Fed. Cir. 1985)).

In his decision the Special Master determined that the BioLumix device infringed on the '873 patent under the "triple identity" test. The Special Master specifically focused on Claim 1 of Centrus' patent, that patents a "barrier layer . . . composed of a matrix phase . . . said barrier layer providing a barrier to solid substances introduced into [the] fluid layer while providing a fluid zone within said matrix which facilitates change in [the] indicator substance and growth media contained in [the] fluid in [the] matrix . . . [when] change occurs [it] can be detected in [the] indicator . . . due to microbial growth occurring in said fluid layer."

Pursuant to this Court's Order [180] accepting the Special Master's Report [147] on *Markman* claim construction, "barrier layer," which refers to the layer of agar in Centrus' device, is defined as "a semi-fluid substance comprised of gel material, having a fluid portion with the same composition as the fluid layer." "Barrier" is defined as "the semi-fluid substance which prevents solids from entering the barrier layer."

Accordingly, in assessing whether the BioLumix device infringed on the '873 patent, the question is whether the "element" identified by BioLumix as making their device "substantially different" from the Centrus device, the "thin membrane," is equivalent to the agar "barrier layer" in the Centrus device, that is, a "a semi-fluid substance comprised of gel material, having a fluid portion with the same composition as the fluid layer." Thus, the Court asks whether there is no genuine issue of material fact as to whether the "thin membrane" in BioLumix' device is equivalent in function, in the way that it performs the function, and in the result, as to the agar "barrier layer" in Centrus' device.

The Court finds that there is a genuine issue of material fact as to whether the BioLumix's thin membrane is equivalent to that of the agar gel barrier layer in Centrus' device. A reasonable jury could find that the two devices are not equivalent. The agar barrier layer's function in the '873 patent is to "provid[e] a barrier to solid substances introduced into [the] fluid layer while providing a fluid zone within said matrix which facilitates change in [the] indicator substance and growth media contained in [the] fluid in [the] matrix." In the case of the BioLumix device, the thin membrane functions *only* to provide a barrier between solid substances introduced into the upper "incubation zone" and the lower "reading zone."

Defendant argues that the "this distinction is completely irrelevant for infringement purposes," and argues that the thin membrane of the BioLumix device is still a part of the "barrier layer." Def.'s Resp. to Obj. at 4. Defendant argues that "[t]here is nothing in the Patent . . . that indicates that the entire barrier layer must be made of a single homogeneous substance . . . [and] nothing in the specifications or the prosecution history that requires that the matrix/barrier material occupy the entirety of the detection zone." *Id.* The Court disagrees. Claim 1 specifically refers to a "barrier layer . . . composed of a matrix phase . . . said barrier layer providing a barrier to solid substances introduced into [the] fluid layer while providing a fluid zone within said matrix . . . ." Thus, it is clear from the language of the claim itself that in Centrus' device the "barrier layer," defined by the Court as "a semi-fluid substance comprised of gel material, having a fluid portion with the same composition as the fluid layer," in fact consists of "a single homogeneous substance" and, in fact, "occup[ies] the entirety of the detection zone." The BioLumix device divides the barrier and the fluid zone into two separate areas of the device, and does not use agar to fulfill a dual role, as found in the Centrus device.

Thus, while both the BioLumix device and the '873 patent share the same function and result, the Court finds that Defendant has failed to demonstrate that there is no genuine issue of material fact as to whether the "way" in which they achieve this result is equivalent.

B. Second and Third Objection - Comments Regarding "Designing Around" Patent, General Weighing of Evidence

Plaintiffs criticize the Special Master's comment in his Report that their device was intended to "design around" the '873 patent. Plaintiffs also generally criticize the Special Master's weighing of the evidence.

Defendant argued, and the Special Master agreed, that despite the separation of the agar barrier layer in the BioLumix device into two separate areas (the thin membrane barrier and the fluid layer beneath the barrier), there was no genuine issue of material fact as to whether the BioLumix device was equivalent to the '873 patent in the "way"it carried out its function. The Court has already determined that there is a genuine issue of material fact as to this question.

The Special Master concluded that, even if the thin plastic membrane was "superior in some respects to agar or gel substances . . . there is no evidence here to support the idea that the modification . . . of the '873 device to the BioLumix device was anything but an effort to 'design around' a patented device to avoid infringement."

Plaintiffs are correct in noting that:

> "[D]esigning or inventing around patents to make new inventions is encouraged." *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir.1991). "[K]eeping track of a competitor's products and designing new and possibly better or cheaper functional equivalents is the stuff of which competition is made and is supposed to benefit the consumer. One of the benefits of a patent system is its so-called "negative incentive" to "design around" a competitor's products, even when they are patented, thus bringing a steady flow of innovations to the marketplace." *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36, (Fed. Cir.1985).

Westvaco Corp. v. Int'l Paper Co., 991 F.2d 735, 745 (Fed. Cir. 1993).

However, the Special Master based his ruling not on the question of whether Plaintiffs had "designed around" Defendant's device, but rather on the question of whether Plaintiffs' device was equivalent to Defendant's device. As noted above, the Court has already found that there is a genuine issue of material fact as to whether Plaintiffs' device is equivalent to Defendant's device. As such, Plaintiffs' objection as to the Special Master's weighing of evidence and comments that Plaintiffs had not shown that they were simply "designing around" Defendant's device is moot.

C. Fourth Objection - Prosecution History Estoppel

Plaintiffs' brief final objection concerns the Special Master's finding that prosecution history estoppel did not apply to Defendant's claims of infringement. Plaintiffs argue that "if the patent applicant made an argument or amendment related to patentability before the United States Patent and Trademark Office . . . the patentee is presumptively completely barred from asserting infringement under the doctrine of equivalents." Pls.' Mot. at 15. This is an oversimplification of prosecution history estoppel.

A change in prosecution claim history "not related to avoiding the prior art . . . may introduce a new element, but it does not necessarily preclude infringement by equivalents of that element." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 33 (1997). The "burden [is] on the patent holder to establish the reason for an amendment required during patent prosecution." *Id.* A court then decides "whether that reason is sufficient to overcome prosecution history estoppel as a bar to application of the doctrine of equivalents to the elements added by that amendment." *Id.* If no reason is provided, "the court should presume that the patent applicant had a substantial reason related to patentability for including the limiting element added by amendment." *Id.*

Here, the Special Master found that Defendant amended its patent claim before the United States Patent and Trademark Office to state that the "barrier layer" in their device was a "matrix"

as distinguishable from the "solid support material" used in a prior patented device.[1] The amendment was not related to the features that Plaintiffs claim distinguishes their device from Defendant's patent (i.e., the presence of a plastic membrane and the separation of the function of the agar barrier layer in Defendant's device into two layers in Plaintiffs' device). Thus "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue." *Honeywell Int'l Inc. v. Hamilton Sunstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (citations omitted).

Plaintiffs, in their objection, offer no substantive response to the Special Master's finding, and the Court, having reviewed the prosecution claim history, agrees with the Special Master's finding. Accordingly, Plaintiffs' fourth objection is denied.

D. Conclusion as to Plaintiffs' Objections

For the reasons stated above, the Court grants Plaintiffs' objection as to the Special Master's finding that there was no genuine issue of material fact as to Plaintiffs' infringement on the '873 patent. The Court finds that there is a genuine issue of material fact as to whether the BioLumix device is equivalent to Defendant's device. Accordingly, Defendant's Motion for Partial Summary Judgment [209] is DENIED as to the '873 patent. Plaintiffs' Motion for Partial Summary Judgment [212] is similarly DENIED.

IV. Defendant's Objections

Defendant objects to the Special Master's finding of non-infringement by Plaintiffs with respect to the '576 patent, the "testing instrument." First, Defendant argues that the Special Master misapplied the *Markman* claim construction previously applied by the Special Master and approved by the Court. Second, Defendant argues that the Special Master's determination that Plaintiffs' BioLumix system could not be calibrated without calibration vials was improper. Third, Defendant argues that the Special Master erred in applying "prosecution history estoppel" to their '576 patent claim. Fourth, Defendant argues that the Court should find that Plaintiffs infringed on the '576 patent through the "doctrine of equivalents."

[1]The "Turner" patent, U.S. Patent 4,945,060.

A. First, Third, and Fourth Objections - *Markman* Claim Construction, Prosecution History Estoppel, and Infringement under Doctrine of Equivalents

Centrus objects that the Special Master erred in finding that Plaintiffs should be granted summary judgment on the '576 patent because the BioLumix device does not infringe directly or by equivalents according to the claim construction approved by this Court and the actual patent prosecution history. Centrus argues that the Special Master misapplied the claim construction set out in this Court's Order [180] approving the Special Master's Report [147]. Centrus also argues that prosecution history estoppel does not apply because Plaintiffs waived the defense by not raising it as an affirmative defense in their Answer.

i. Claim Construction

Claim 1 of the '576 patent is for "an instrument for detecting microbial growth in test vials containing growth media and dye material." The only portion of this claim relevant to the current motions is the following:

> (1) a multiplicity of light-sensor combinations, each combination comprising at least one light source and at least one light detector positioned at the location of each of the *test vials*, said light detector positioned relative to said light sensor to detect light emitted from the
> dye material when said light source illuminates said dye material;
> (6) said algorithm comprising the formula: Y=X(U-L)/(OL-LL) + U-OL(U-L)/(OL-LL), wherein: X is the output from said light source;
> Y is said compensated value; U is a desired maximal level common to all said compensated levels; L is a desired minimal level common to all said compensated levels; *OL is the output of said light detector receiving energy directly from the light source when said test vial is being removed*; and LL is the output of said light detector when said light source is driven by said driver means at a level representing the minimal energy obtained from said light detector for any of said test vials.

(Emphasis added).

Pursuant to the Order [180] accepting the Special Master's Report [147] on *Markman* claim construction, "OL . . . when said test vial is being removed" is clarified to mean "OL . . . when no test vial is positioned between the source and the sensor." "Test vial(s)" is defined as "vial(s) containing samples to be tested for microbial growth, growth media, and dye material."

Finally, in the prosecution claim history of the '576 patent, under the "PREFERRED EMBODIMENT" heading, the following is stated: "In the preferred embodiment the system is 'self calibrating' *without employing any standard reference vials*" (emphasis added). In the preferred embodiment calibration process, step 2 relates to determining the Open Level (OL), referred to in the algorithm above. "[The OL level is] obtained when the vial is taken out of the system . . . ." The Special Master also noted that another variable, the Low Level Position (LLP) is obtained "without a reference vial," and thus means there is no need "to employ actual vials containing standard dyes during the calibration process."

The Special Master found that the BioLumix device does not infringe on the '576 patent because the BioLumix device cannot be calibrated without the use of reference vials. Because the BioLumix device uses reference vials to calibrate, rather than "through-the-air" calibration, the BioLumix device cannot meet the claim definition of the '576 patent, because the "OL" portion of the algorithm specifically refers to the direct receipt of light energy that takes place when "said test vial is . . . removed."

Defendant's objection relies on a strained reading of the patent claim history and the preferred embodiment process. Defendant argues that there are actually two kinds of vials involved in its patent: test vials, and "reference" or calibration vials. Defendant argues that their patent claim is for a device that, in its "preferred embodiment" calibrates without the use of a "standard reference vial," but that the patent was "clear that the calibration could be performed with or without standard reference vials . . . and expressly disclosed an embodiment that used standard reference vials." Def.'s Obj. at 4. Defendant further argues that what permitted the patent of the '576 patent over the prior art was the specific algorithm used by the '576 device, "rather than an overarching requirement for a calibration vial-free calibration."

What is clear from the patent history, the patent itself, and Centrus' argument is that Centrus' attempted distinction between various types of vials was not contemplated in the patent. Rather, the patent is for a device that can calibrate without the use of test vials present in the device.

As noted above, the patent itself contains references only to "test vials." The description of the algorithm, which Centrus argues was what distinguishes the '576 patent from the prior art, contains a reference to a value "OL," meaning "Open Level." In the patent itself, this value is noted as "OL . . . when said test vial is being removed." In this Court's *Markman* order establishing claim construction, this statement was clarified to mean "OL . . . when no test vial is positioned between the source and the sensor," utilizing the same terminology as used in the patent claim language itself. Accordingly, pursuant to this Court's order on claim construction and the patent itself, a central value necessary for the algorithm in the '576 patent is obtained "when said test vial is being removed," i.e., "when no test vial is positioned between the source and the sensor." Therefore, the '576 patent is distinguished from the prior art by the lack of a test vial during calibration.

Defendant argues that the Court should look to one section of the patent history, the "Summary Objects and Advantages" section, in which it is stated that an objective of the invention is "to provide a 'self calibration' scheme that the user can apply periodically with or without standard reference vials." Defendant argues that this language indicates that the '576 patent is *not* distinguished by its ability to calibrate without vials, because said language indicates that the device may be calibrated with or without standard reference vials. However, as noted above, throughout the remainder of the '576 claim and the patent history, there are consistent references to the lack of a vial in the device during calibration. The Court does not find that there is any genuine issue of material fact as to this question.

Even if the Court sets aside the numerous statements in both the patent claim and in other sections of the patent history that indicate that the '576 device is intended to calibrate without the presence of reference vials, however, and accepts that the '576 device can successfully calibrate even with the presence of a transparent "reference vial," this does not avail Defendant. The Court has already determined, based on the language of the patent claim and on the Court's own *Markman*

claim construction, that it is the ability to calibrate without the presence of vials that distinguished the '576 from prior art and that is the subject of the patent, based on the "OL" portion of the algorithm that specifically contemplates the removal of a test vial to obtain the OL value.

Defendant also argues that even if the OL is obtained "when the vial is taken out of the system, and the light source . . . travels through the air and hits the light sensor . . . without the influence of the dye," that this does not preclude the use of "calibration vials" to obtain the OL. Defendant asserts that its "calibration vials" unlike "test vials," do not contain dye and are clear, and that despite the reference in the Specification to the light "traveling through the air," and the language in the patent claim referring to the "test vial" "being removed," that the patent contemplates the light traveling "as well, through the dye-free calibration vial." Defendant posits that the specification refers "to the absence of dye, rather than the absence of vials of any kind." Thus, Defendant argues, when the Specification refers to an "open condition (no vials)" it actually means "no vials containing dye."

The Court rejects this nonsensical reading of the patent history. Reasonably read, the reference in the specification to "no vials" means that the machine calibrates in the open condition without vials, and obtains the OL value without the presence of vials.

ii. Prosecution History Estoppel

Defendant argues that Plaintiffs cannot raise prosecution history estoppel claims (i.e., that Defendant is estopped in its application of the doctrine of equivalents by any narrowing of the patent claim in the patent prosecution history) because Plaintiffs did not raise prosecution history estoppel as an affirmative defense in their Answer. Defendant relies on *Carman Indus., Inc. v. Wahl*, 724 F.3d 932, 942 (Fed. Cir. 1983), in which the Federal Circuit found that prosecution history estoppel had been waived because it had not been argued before the district court. The court referred to estoppel as "an affirmative defense," but notably refused to apply estoppel not because it had not been raised in the Answer, but rather because it had not been raised before the district court. Similarly, in *Yeu v. Kim*, 904 F.2d 44, at *2 (Fed. Cir. May 3, 1990) the court declined to state whether a party was precluded from raising prosecution history estoppel because it was an

affirmative defense, but instead simply noted that it was "unpersuaded that [the defendant] has excused their failure to timely argue a prosecution history estoppel defense."

These seemingly at-odds decisions have been clarified by other courts. As noted in *Advanced Cardiovascular Systems, Inc. v. Medtronics, Inc.*, 1996 WL 467273, at *4 (N.D. Cal. July 24, 1996), "[s]ince prosecution history estoppel is only applicable where the doctrine of equivalents has been raised as a means of constructing an infringement claim, prosecution history estoppel is not an affirmative defense," and concluded that *Carman Industries*, above, referred to prosecution history estoppel being raised for the first time on appeal.

The Court agrees with this analysis, particularly given that Defendant did not raise the doctrine of equivalents as part of their claim in their Counter-Complaint [66] or Amended Counter-Complaint [69], instead stating in all claims that Plaintiffs had "directly infringed" the patents at issue. It would have made little sense for Plaintiffs to have raised prosecution history estoppel at a stage when the doctrine of equivalents had not been mentioned when "[p]rosecution history estoppel is a defense to the assertion of the doctrine of equivalents." *Advanced Cardiovascular Systems, Inc.* 1996 WL 467273, at *4. Accordingly, Plaintiffs have not waived prosecution history estoppel as a defense.

Defendant next argues that prosecution history estoppel does not apply because there are exceptions to the "presumption" of estoppel created by the narrowing of a patent claim during patent claim prosecution. Defendant argues that the presumption applicable here is that "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent at issue." *Honeywell Int'l Inc. v. Hamilton Sunstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (citations omitted). Defendant argues that "the purpose of the amendment was not to restrict the scope of the claim to a calibration system that does not use calibration vials," Def.'s Reply to Pls.' Obj. [246] at 10, but rather to restrict the scope of the claim to "the use of an algorithm using the variables as recited in claim 4." However, the very algorithm Defendant acknowledges was the focus of the narrowing amendment is the algorithm discussed, *supra*, containing the OL value that can only be obtained without the presence of calibration vials. Accordingly, the Court finds that the

"rationale underlying the narrowing amendment" bears a substantial relationship to the equivalent at issue.

Accordingly, the application of prosecution history estoppel is appropriate.

iii. Doctrine of Equivalents

Because the Court finds that prosecution history estoppel applies, and moreover finds that the Special Master correctly determined that Defendant's infringement claim as to the '576 patent is precluded by the Court's claim construction because the Biolumix device cannot be calibrated without reference vials, the Court does not reach Defendant's objection that it should find infringement under the doctrine of equivalents.

B. Second Objection - Ability of BioLumix Device to Calibrate without Vials

Defendant next argues that the BioLumix device in fact has the ability to calibrate correctly without the presence of reference vials, and therefore infringes on the patented algorithm discussed above, that is patented based upon obtaining an OL value without the use of reference vials. Plaintiffs respond that the BioLumix device cannot calibrate in a correct and consistent manner without the use of a calibration vial, and also note that a modification to the BioLumix device put into place. Defendant replies by arguing that Plaintiffs' expert's report is unsworn and hearsay at the summary judgment stage.

I. Waiver

Defendant argues that there "was no basis for the Special Master to have considered [Plaintiffs' expert's reports] in granting summary judgment . . . ." Def's Reply to Obj. at 7. The Court notes at the outset that the Special Master did not rely on Plaintiffs' expert's report because Defendant failed to raise this factual issue before the Special Master, despite Plaintiffs themselves asserting in their summary judgment briefs that the BioLumix device could not calibrate correctly without the use of reference vials. *See* Pls'. Mot. for Partial Summ. J. [212] at 19-20 ("If calibration vials are not used with the BioLumix instrument, the user will not get consistently accurate test results"). Defendant did not respond to this argument in their briefs to the Special Master. Only in its objection did Defendant argue for the first time that there is a factual dispute as to whether the

BioLumix device requires calibration vials to obtain accurate test results. Acting in the place of this Court, the Special Master "is not required to speculate on which portions of the record the nonmoving party relies, nor is it obligated to wade through and search the entire record for some specific facts that might support the nonmoving party's claim." *InterRoyal Corp. v. Sponseller*, 889 F.2d 108, 111 (6th Cir. 1989). Accordingly, the Special Master did not err in finding that there was no genuine issue of material fact as to whether the BioLumix device was capable of calibrating accurate without calibration vials.

In addition, arguments raised for the first time in objections to the report and recommendation of a Magistrate Judge are deemed waived. *See Murr v. United States*, 200 F.3d 895, 902 n.1 (6th Cir. 2000) (citing *United States v. Waters*, 158 F.3d 933 (6th Cir. 1998) ([W]hile the Magistrate Judge Act, 28 U.S.C. § 631 *et seq.*, permits *de novo* review by the district court if timely objections are filed, absent compelling reasons, it does not allow parties to raise . . . new arguments or issues that were not presented to the magistrate"); *see also Marshall v. Chater*, 75 F.3d 1421, 1426-27 (10th Cir. 1996) (collecting various cases holding that "issues raised for the first time in objections to the magistrate judge's recommendation are deemed waived").

The Court finds that this waiver applies in equal force to the report of the Special Master, given that the language of the Order of Referral [63] to the Special Master's findings tracks almost identically the language of 28 U.S.C. § 636(b)(1)(c), which discusses review of a Magistrate Judge's findings and recommendations. Indeed, the purpose of appointment of the Special Master was to "provide for a more efficient and orderly adjudication" of the claims of the parties, and this purpose is poorly served by "allowing parties to litigate fully their cases before the magistrate and, if unsuccessful, to change their strategy and present a different theory to the district court . . . ." *Greenhow v. Sec'y of Health and Human Servs.*, 863 F.2d 633, 638.39 (9th Cir. 1988), *overruled on other grounds by United States v. Hardesty*, 977 F.2d 1347 (9th Cir. 1992), *cert. denied*, 507 U.S. 978 (1993). Defendant had ample opportunity to raise this factual dispute before the Special Master in their Motion for Partial Summary Judgment [209], Reply [215], and Response to Plaintiffs' Motion for Partial Summary Judgment [214]. As Defendant failed to do so, the Court deems this argument waived. Accordingly, Defendant's objection is not well-taken.

C. Conclusion as to Defendant's Objections

For the reasons stated above, the Court denies Defendant's objections. Accordingly, Defendant's Motion for Summary Judgment [209] is DENIED as to the '576 patent. Plaintiffs' Motion for Summary Judgment [212] is GRANTED as to the '576 patent.

V. Conclusion

IT IS ORDERED that Plaintiffs' Motion for Partial Summary Judgment [212] is **GRANTED** on the issue of non-infringement with respect to the '576 patent. Plaintiffs' Motion for Partial Summary Judgment is **DENIED** with respect to the '873 patent. Defendant's Motion for Partial Summary Judgment [209] is **DENIED** as to both the '576 and '873 patents.

SO ORDERED.

s/Arthur J. Tarnow
Arthur J. Tarnow
Senior United States District Judge

Dated: December 3, 2012